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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/314,540	05/19/99	LANGER R	0492611-0335

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EXAMINER	
MARTINELL,J	
ART UNIT	**PAPER NUMBER**
1633	12

DATE MAILED: 05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/314,540	LANGER ET AL.	
	Examiner	Art Unit	
	James Martinell	1633	

-- Th MAILING DATE of this communication appears on the cov r sh et with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54 and 64-72* is/are pending in the application.

4a) Of the above claim(s) *18-54 and 69-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 64-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Claims 18-54 and 69-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 64-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The recitation of "biological recognition event" (claims 1, 2, and 66) is vague and indefinite because the instant application does not define the term and because there is no art-accepted meaning or definition of the term. Additionally, the application does not distinguish between a biological recognition event and a non-biological recognition event. Hence, the metes and bounds of the claims are unclear.

(b) The recitation of "biomaterial architecture" (claims 2, 6, 7, and 64-68) is indefinite because the instant application does not define the term and because there is no art-accepted meaning or definition of the term. Additionally, the application does not distinguish between biomaterial architecture and a non-biomaterial architecture. Hence, the metes and bounds of the claims are unclear.

(c) The recitation of "involves" (claim 2) is vague and indefinite because it is unclear what the term embraces in context of the claim.

(d) Claims 2, 4, 5, and 8 are confusing in that they use process terminology, but not product by process terminology, in composition claims. It is unclear whether these are intended as limitations on the claims, and if they are, just what the limitations on the composition claims are.

(e) The recitation of "biologically relevant molecule" (claims 6 and 64) is vague and indefinite because the instant application does not define the term and because there is no art-accepted meaning or definition of the term. Additionally, the application does not distinguish between biologically relevant molecules and biologically irrelevant molecules. Hence, the metes and bounds of the claims are unclear.

(f) The recitation of "biomolecular interaction" (claims 6 and 64) is vague and indefinite because the instant application does not define the term and because there is no art-accepted meaning or definition of the term. Additionally, the application does not distinguish between a biomolecular and a non-biomolecular interaction. Hence, the metes and bounds of the claims are unclear.

(g) The recitation of "desired ligand" (claims 6 and 64) is vague, indefinite, and incomplete because there is no criterion recited upon which to base a decision, and hence a desire.

(h) The recitation of "PLA-PEG" (claim 9) is vague and indefinite. The claim should recite the names of the compounds rather than their acronyms.

(i) Claim 10 is vague and indefinite because it recites a Markush group improperly. See MPEP 2173.05(h).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 16, and 64-68 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hoffman, *Artificial Organs* 16: 43 (1992). Hoffman discloses (see entire document) materials for use in tissue engineering that meet all of the limitations of each of the claims (*e.g.,* nucleic acids and antibodies, pages 44 and 45).

Claims 1-17 and 64-68 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Patel et al, *FASEB J.* 12: 1447 (1998). The reference discloses the claimed invention. The declaration by Dr. Cannizaro under Rule 132 and filed October 3, 2000 is not persuasive because the declaration does not disclose facts in connection with the material in the publication and the level of contribution of each of the authors in connection with what is in the publication. The CCPA in *In re Katz* (215 USPQ 14, 1982) determined that a declaration concerning actions of authors in a publication is not a mere restatement of the filing oath or declaration.

Claims 15 and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by either one of Diamandis et al *Clin. Chem.* 37: 625 (1991) or Pardridge et al (WO 92/22332 (December 23, 1992)). The claims describe no more than the biotin-avidin systems disclosed in the references (*e.g.,* Diamandis et al, pages 632-633 and Pardridge et al Abstract and Claims).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The examiner can normally be reached on Tuesdays through Thursdays and Saturdays from 8:00 A.M. to 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah R. Clark, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JAMES MARTINELL, Ph.D.
SENIOR LEVEL EXAMINER